REMARKS

Claims 1-7, 9-16, 18-21 and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over various combinations of US Pat. 5,916,244 (Walters), US Pat. 4,989,607 (Keusch et al.), US Pat. 4,419,998 (Heath), and US Pat. 5,817,151 (Olson et al.). Claim 1 describes an electrode comprising an electrode body having a first and second side, wherein the first side comprises a flexible moisture barrier layer comprising a heat-sealable material and the second side comprises a conductive layer; an electrically conductive gel layer disposed on the electrode body and which is further in electrical communication with the conductive layer, the periphery of the heat-sealable moisture barrier layer extending beyond the periphery of the gel layer; and a rigid release liner heat-sealed to said flexible barrier layer around the periphery of said gel layer.

In the past, defibrillators were found only in hospitals and with emergency aid units. In these environments the defibrillators were used fairly regularly, which meant that electrodes were only stored short periods of time before being used, similar to ECG electrodes which are generally used in greater quantity and even more rapidly. As such, the possibility that an electrode would dry out and become unusable was not a problem. But with the advent of automatic external defibrillators (AEDs) in the mid-1990s, this use model changed. The Examiner has no doubt seen AEDs on the walls of airport, malls and office buildings where they are available for use immediately when someone nearby is stricken with cardiac arrest. When an AED is needed it is needed at once to save the life of the victim, and it must be in a state where it can be used at once without fail. This means that an AED can sit in its case on the wall for months or even years, and must then be usable at once. Accordingly, the electrode pads with the AED must be preserved in an air-tight environment so they will not desiccate during this long storage time, with the gel being moist and ready to use as soon as they are removed from their package. If the electrodes were to dry out during their extended storage, the AED would read an inaccurate impedance between the electrodes and fail to deliver its life-saving shock.

The conventional way to store electrodes is in a moisture-impermeable pouch which is generally made of a foil or a polymer. The cited patents show such pouches. For instance, Keusch et al. refers in col. 14, lines 29-34 to storage of their electrodes in a sealed packet or envelope. Olson et al. describe their electrodes as stored in a sealed polymer or polymer-metal laminate package 60. See also the Olson et al. 5,645,571 patent which describes the same package 60. Heath uses a sealing cover 83 which fits over the electrode

and sticks to a layer of adhesive applied for this purpose on a ring 79around the outer edge of the electrode.

Walters, however, does not disclose any moisture-impermeable package for his electrodes. Walters does describe a typical thin release liner sheet 44 which covers the hydrogel of his electrodes. The purpose of this sheet is not to hermetically seal the hydrogel, but to protect it as Walters says from inadvertently sticking to other materials. Such release liner sheets also conventionally cover ECG electrodes and are peeled off just prior to use of the electrode. The release liner also prevents the tacky hydrogel from picking up dust, dirt, and other debris which could render it unusable. But these release liners cannot prevent the electrodes from drying out, as the hydrogel is still exposed to the air around the periphery of the hydrogel. To prevent the hydrogel from drying out, they must still be stored in an air-tight container.

But these envelopes, pouches and packages give a rescuer using an AED another task, which is to tear open the package to retrieve the electrodes for use. Often the envelopes or pouches will be sealed around the electrode wires (see the illustration on the cover of the Olson et al. '571 patent, for example), and will dangle from the wires during use, getting in the way of the rescue. Furthermore, these envelopes, pouches, and packages are an additional expense when manufacturing an electrode set and increase the cost of the electrodes. The present invention overcomes these problems in a synergistic way that is not suggested by any of these references.

The Examiner minimizes the claimed invention as the use of a rigid release liner, with all other elements being known. It is respectfully submitted that the present invention is considerably more than that. First, the claimed invention is an electrode with a moisture-impermeable backing made of a material which can be heat-sealed. Thus, the backing of the electrode itself is part of the moisture-impermeable enclosure for the hydrogel. Second, the electrode is place with its hydrogel side against a moisture-impermeable release liner and the periphery of the electrode backing is heat-sealed to the release liner. The firm heat seal around the periphery of the electrode thus hermetically seals the hydrogel in a compartment formed of the release liner and the backing of the electrode itself. No separate pouch or envelope is needed. No adhesive is needed. Because the heat seal is so firm, removing the electrode from the release liner is not as easy as peeling the standard thin Walters release liner sheet off of the tacky hydrogel. The present inventors have found that the release liner needs to be a rigid sheet to aid in removal of the electrode from the release liner; a thin release liner sheet of the prior art makes the task too difficult to perform easily. And when

the electrode is removed from the rigid release liner, there is no package or pouch or envelope dangling from the wires or needing disposal. There is only the rigid release liner card to be set aside while the rescue proceeds. The absence of a pouch or package or envelope simplifies the manufacturing operation and reduces cost, providing a long-storage-life electrode in a cost-effective way.

In summary, Walters has a release liner 44 which covers the hydrogel of his electrode, but no moisture-impermeable package for his electrodes. Keusch et al. calls for a sealed pouch or envelope in which to store his electrodes to prevent desiccation. Heath has a sealing cover 83 which fits over the electrode and sticks to an adhesive on a ring 79 around the edge of the electrode. Olson et al. '151 and '571 store their electrodes in a pouch type package 60. It is respectfully submitted that none of these patents or their combination suggests the inventors' unique and simple approach of no package at all, but rather peripheral heat-sealing of the electrode backing to a rigid release liner, which forms a moisture-impermeable compartment of the electrode backing itself and the release liner.

For these reasons it is respectfully requested that the Examiner reconsider the decision in this case and allow Claims 1-7, 9-16, 18-21 and 23.

In light of the foregoing remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

ERIC JONSEN ET AL.

By: /W. Brinton Yorks, Jr./
W. Brinton Yorks, Jr.
Reg. No. 28,923

Philips Electronics
22100 Bothell Everett Highway
P.O. Box 3003
Bothell, WA 98041-3003
(425) 487-7152
January 19, 2009